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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/414,384	10/07/99	CLARK	A 0037.00

021968 QM32/0607
INHALE THERAPEUTIC SYSTEMS, INC
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EXAMINER	
LEWIS,A	
ART UNIT	**PAPER NUMBER**
3761	12

DATE MAILED: 06/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/414,384	ANDREW CLARK ET AL.
Examiner	**Art Unit**
AARON J. LEWIS	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 1, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *21-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (EP 0 808 635 A2).

As to claim 21, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphram having a particular flexibility in combination with dimensions of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance.

As to claims 22-25, Howlett, as discussed above with respect to the particular quantity of flow resistance the particular quantity of flow rate can be arrived at through mere routine obvious

experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

As to claims 26 and 27, the particular period of time during which the flow resistance is applied by the device of Howlett will vary with the manner of use of the device. That is, the duration of time during which flow resistance is applied is directly proportional to the duration of a particular patient's inhalation period. Consequently, this time period can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular time period.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant devices for providing a resistance to flow during patient inhalation on aerosol medicament producing devices.

Response to Arguments

4. Applicant's arguments with respect to claims 21-27 have been considered but are moot in view of the new ground(s) of rejection.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

June 4, 2001

Aaron J. Lewis
Primary Examiner